

EXHIBIT 3

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-229

APPROVED DRAFT LABELING

NDA 21-229: Prilosec OTC™; Item 2 – Revised Draft Labeling (16 June 2003)
 Appendix 2.6 – Trial Sample Size Labeling

NEW!

FREE of new **Prilosec OTC**
STARTER KIT

Prilosec OTC
 30 mg Delayed-Release Tablets

Prilosec OTC
 30 mg Delayed-Release Tablets

Prilosec OTC
 30 mg Delayed-Release Tablets

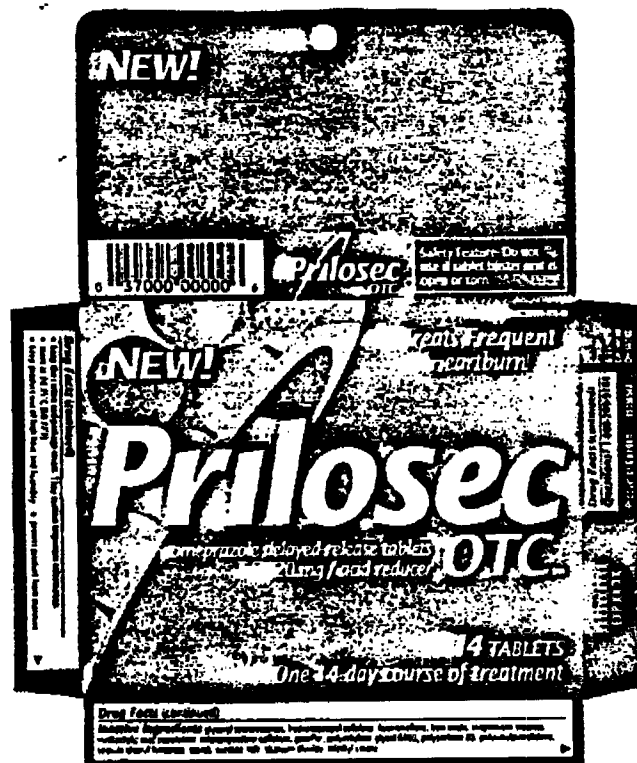
Treats Frequent Heartburn

Experience the first couple of days of your 14-day course of treatment!
 Follow samples with a 14 day course of treatment. Read label on back before use.

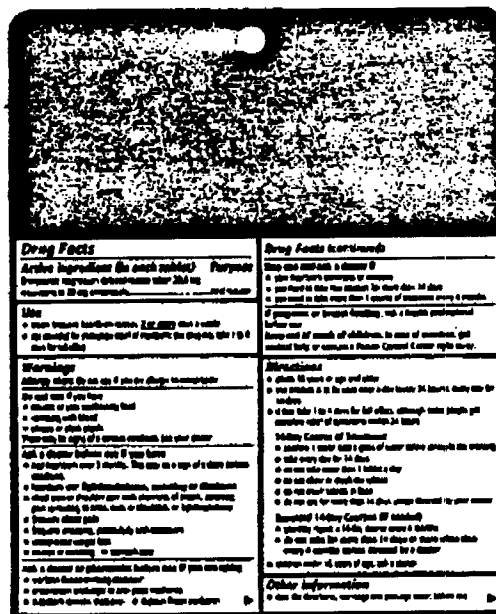
NDA 21-229: Prilosec OTC™: Item 2 – Revised Draft Labeling (16 June 2003)
Appendix 2.6 (Cont'd) – Trial Sample Size Labeling

Drug Facts Active ingredient (in each tablet) Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole)	Drug Facts (continued) If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Purpose Acid reducer	Directions • adults 18 years of age and older • this product is to be used once a day (every 24 hours), every day for 14 days • it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
Use • treats frequent heartburn (occurs 2 or more days a week) • not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect	14-Day Course of Treatment • swallow 1 tablet with a glass of water once a day before eating • take every day for 14 days • do not take more than 1 tablet a day • do not chew or crush the tablets • do not crush tablets in food • do not use for more than 14 days unless directed by your doctor
Warnings Allergy alert: Do not use if you are allergic to omeprazole. Do not use if you have • trouble or pain swallowing food • vomiting with blood • bloody or black stools These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with nighttime, swelling or dizziness • chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness • frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain	Repeated 14-Day Courses (if needed) • you may repeat a 14-day course every 4 months • do not take for more than 14 days or more often than every 4 months unless directed by a doctor • children under 18 years of age: ask a doctor
Ask a doctor or pharmacist before use if you are taking • warfarin (blood-thinning medicine) • prescription antifungal or anti-yeast medicines • diazepam (anxiety medicine) • digoxin (heart medicine) Stop use and ask a doctor if • your heartburn continues or worsens • you need to take this product for more than 14 days • you need to take more than 1 course of treatment every 4 months	Other Information • read the directions, warnings and package insert before use • keep the carton and package insert. They contain important information. • store at 20-25°C (68-77°F) • keep product out of high heat and humidity • protect product from moisture Inactive ingredients ptyrene monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polyorbate 30, polyvinylpyrrolidone, sodium stearoyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate
Questions? 1-800-759-4841	Questions? 1-800-759-4841

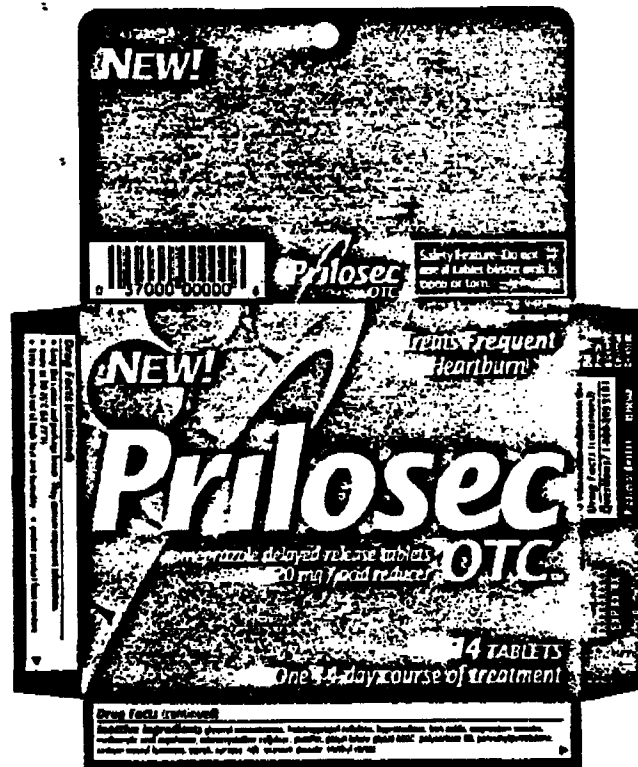
Product of Sweden
Dist. by Procter & Gamble, Cincinnati, OH 45202
42431715



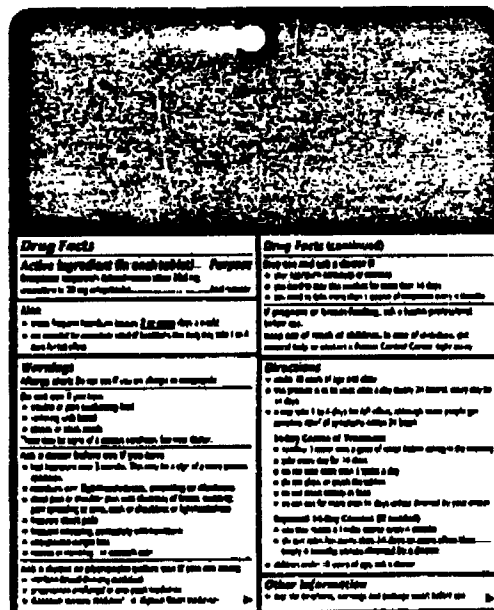
14 ct carton with tab



Back



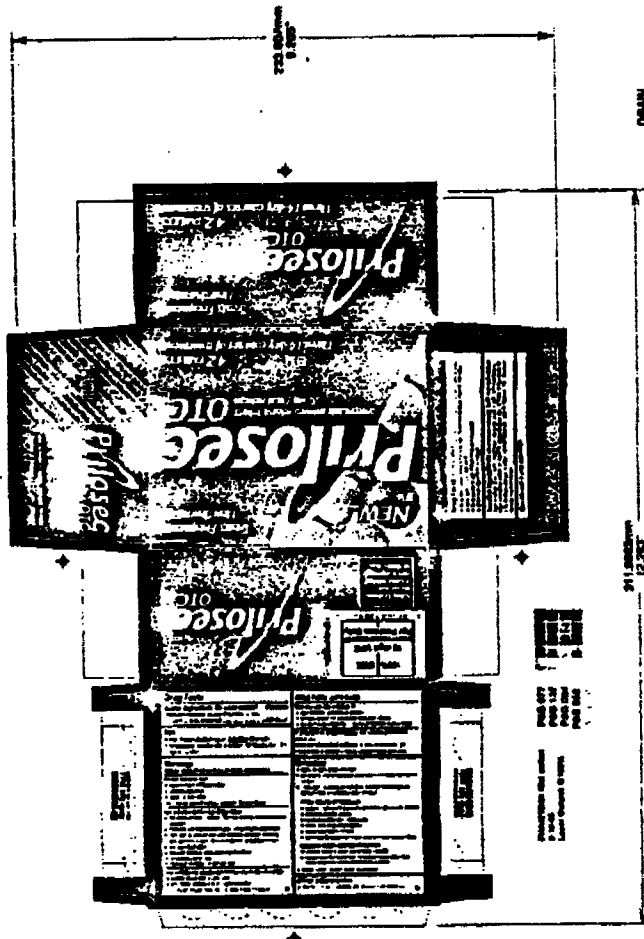
14 ct carton with tab



Back

[illegible]

42ct Ptilosec Outer Carton (holds three 14ct cartons)



THE PRODUCT'S SAMPLE CO
NAME
ADDRESS
CITY
STATE
ZIP
COUNTRY

PRINTED IN THE U.S.A.
UPC 000000

1) Each segment each 14ct OTC. Each segment is printed on the top of the carton and also on the side. Each segment is for individual 14ct OTC. 100% Recycled Paper.

2) See material Specification for manufacturers plus the necessary information.

FINAL ARTWORK APPROVAL

UPC 000000

1) Each segment each 14ct OTC. Each segment is printed on the top of the carton and also on the side. Each segment is for individual 14ct OTC. 100% Recycled Paper.

2) See material Specification for manufacturers plus the necessary information.


**X = 21 mm to center
of eyemark
Web width = 129.1 mm
Cutoff = 208.5 mm
Spacers from start
of imprint = 10mm
Eyemark = 4mm x 12mm**

Web width = 128.1 mm

Cutoff = 209.5 mm

Spareout from start

of Imprint = 10mm

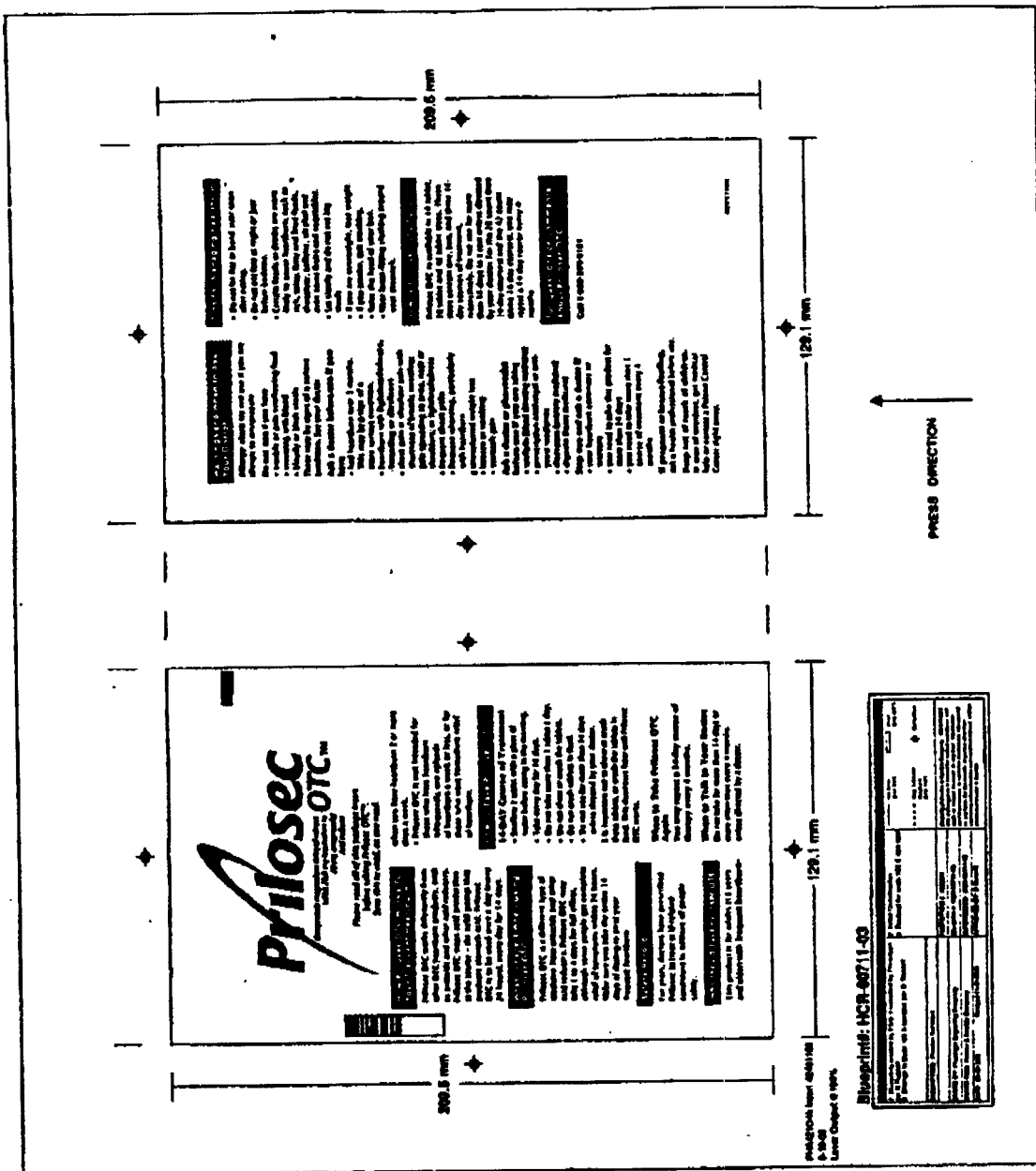
 **THE PROCTER & GAMBLE CO.**
HEALTH CARE

MACROBID 100	MACROBID 100
100 mg capsules	100 mg capsules

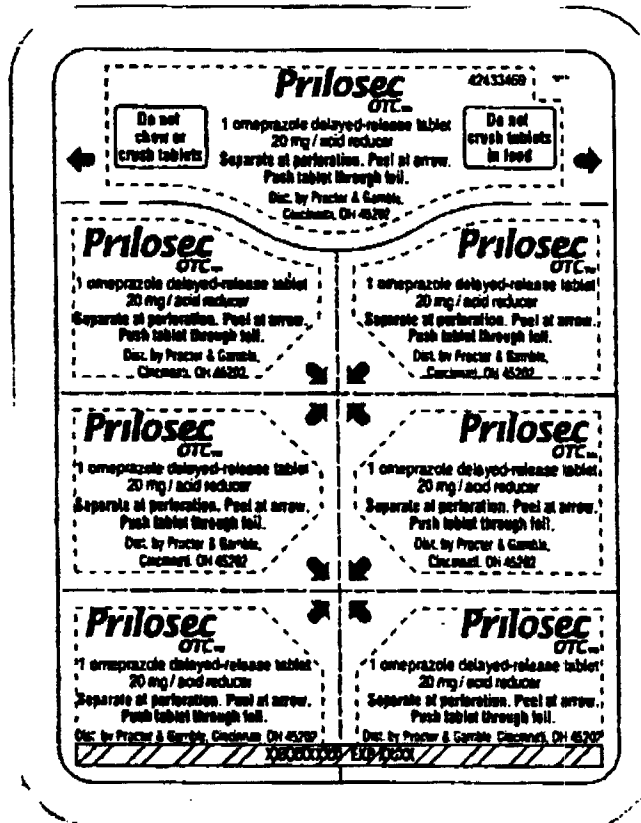
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1. Code 128 is to be placed on the label that is located on the glass ampoule. The code is of 10% concentration, only label is 128, is to be placed.

FINAL NETWORK APPROVAL			
LIPSON ALPHEE GLASS & ASSOCIATES			
<small>1000 S. 10th Street, Suite 100, Portland, Oregon 97204 Phone: (503) 228-1234 Fax: (503) 228-5678</small>			
PROJECT INFORMATION PROJECT NO: 001 CLIENT: ABC Corp. DATE: 10/26/00	STUDY/DISPOSITION DATE: 10/26/00 BY: J. Smith REVISIONS:	COMPUTER EQUIPMENT <div style="display: flex; justify-content: space-around;"> <div>PC 1</div> <div>PC 2</div> <div>PC 3</div> </div>	
PHYSICAL OF LEADY BOLL STOCK DATE: 10/26/00 BY: J. Smith REVISIONS:		TESTS, BUSICTIONS <div style="display: flex; justify-content: space-around;"> <div>TEST 1</div> <div>TEST 2</div> <div>TEST 3</div> </div>	
PHYSICAL OF LEADY BOLL STOCK DATE: 10/26/00 BY: J. Smith REVISIONS:		TECHNICAL MEASUREMENTS DATE: 10/26/00 BY: J. Smith REVISIONS:	
PHYSICAL OF LEADY BOLL STOCK DATE: 10/26/00 BY: J. Smith REVISIONS:		PHYSICAL OF LEADY BOLL STOCK DATE: 10/26/00 BY: J. Smith REVISIONS:	



NDA 21-229: PRILOSEC OTC™
Item 2 – Revised Draft Labeling (16 June 2003)
Appendix 2.5
Blister Card Labeling



NDA 21-229: PRILOSEC OTC™

: Item 2 – Revised Draft Labeling (16 June 2003)

Appendix 2.3

Configuration of Plastic Overlay for 42-Count Package

